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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,464	11/29/2000	Kun Ping Lu	BIZ-045CP	1620

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LAHIVE & COCKFIELD  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

15

DATE MAILED: 04/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/726,464

Applicant(s)

LU ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,4-10 and 13-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-10 and 13-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. The amendment filed 1/8/2003 (paper no 14) is acknowledged and entered into the record. Accordingly, claims 2,3,11,12,25, and 26 are canceled.
2. Claims 1,4-10, and 13-24 are pending and examined on the record.

### ***Information Disclosure Statement***

3. The Information Disclosure Statement filed 2/26/2002 (paper no. 8) is acknowledged and considered. A signed copy of the IDS is attached hereto.

### ***Claim Rejections Maintained - 35 USC § 112, 1<sup>st</sup> paragraph***

4. The rejection of claims 1, 4-10, and 13-24 under 35 USC 112, 1<sup>st</sup> paragraph as lacking an enabling disclosure is maintained for the reasons of record. Applicant argues that claims drawn to the evaluation of Pin1 nucleic acid levels are withdrawn thereby rendering claims enabled. Applicant's arguments and amendments have been carefully considered but are not found persuasive. Although the applicant's cancellation of claims drawn to measuring nucleic acid levels further defines the scope of the invention, applicant has not addressed the type of test sample used in the instant invention. It is understood by the examiner that the Pin1 protein is expressed in the nucleus, and the instant invention is drawn to measuring the levels of the said protein in bodily fluid of which include blood, ascities, or brain fluid. It is still not clear how one of skill in the art would be able to assess the abnormal growth of cells by measuring fluid that is not

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associated with nuclear complexes. As such, the instant specification has only confined the evaluation of Pin1 levels in tissue samples, and no other.

***New Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1,4,7-8,10,13-14,16-17,19-20, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Shen *et al* (Genes and Development 1998;12:706-720, IDS A16). Claims are drawn to a method of comprising assessing Pin1 polypeptide in a test sample, wherein the test sample is an epithelial cell and a malignant cancer selected from a group of which includes cervical cancer. The claims are further limited to a method comprising the steps of detecting Pin1 levels in a test sample and comparing the levels of Pin1 with control samples, wherein the cell is a malignant cancer selected from a group of which includes cervical cancer. The claims are also limited to a method comprising the steps of contacting test sample with a Pin1 antibody, detecting the antibody, and comparing the amount of the complex in the test sample with that of a control sample, wherein the antibody is polyclonal, the cell is a malignant cancer selected from a group of which includes cervical cancer, and further detected by a secondary antibody. Shen *et al* disclose a method of detecting Pin1 in HeLa cells of which are derived from a malignant human cervical carcinoma, and further

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disclose a method of detecting using a polyclonal antibody directed against the Pin1 protein. Because Shen *et al* teach of the effects of Pin1 overexpression, comparisons were made between control samples and samples overexpressing Pin1.

***New Claim Rejections - 35 USC § 102***

7. Claims 1,4-5,7-8, 10,13-14,16-17,19-20, and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Hunter *et al* (WO 97/17986). See above for limitations of claims 1,4,7-8,10,13-14,16-17,19-20, and 24. The claims are further drawn to a the test sample being a body fluid, and wherein method of using an antibody to Pin1 are detected using an antibody that is detectably labeled. Hunter *et al* disclose a method of detecting the level of Pin1 protein in cells derived from malignant human cervical carcinoma cells and in bodily fluids, wherein the Pin1 can be detected using antibodies (labeled or non-labeled) (see page 20, 22, 24).

***New Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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9. Claims 1,4-5,7-8, 10,13-14,16-17,19-20, and 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Hunter *et al* (U.S. Patent 5952467). See above for limitations of claims 1,4,7-8,10,13-14,16-17,19-20, and 24. The claims are further drawn to a the test sample being a body fluid, and wherein method of using an antibody to Pin1 are detected using an antibody that is detectably labeled. Hunter *et al* disclose a method of detecting the level of Pin1 protein in cells derived from malignant human cervical carcinoma cells and in bodily fluids, wherein the Pin1 can be detected using antibodies (labeled or non-labeled) (see columns 13 and 14).

### ***Conclusion***

No claim is allowed.

This office action is made **NON-FINAL** to allow the applicant a chance to respond to the newly cited rejections.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen  
Art Unit 1642  
April 4, 2003



ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
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